| | Diabetic Patients | | | Non-Diabetic Patients | | |
|---|---|---|---|---|---|---|
| Events at 5 years | EES (n=153) | PES (n=172) | p-value | EES (n=744) | PES (n=730) | p-value |
| Death | 15.7% (24) | 14.5% (25) | 0.77 | 7.7% (57) | 9.3% (68) | 0.25 |
| Myocardial Infarction | 9.2% (14) | 13.4% (23) | 0.23 | 6.6% (49) | 11.1% (81) | <0.01 |
| Target Vessel Revascularization | 9.2% (14) | 15.7% (27) | 0.08 | 7.0% (52) | 10.4% (76) | 0.02 |
| Target Lesion Revascularization | 7.2% (11) | 11.0% (19) | 0.23 | 6.0% (45) | 9.2% (67) | 0.02 |
| Def./Prob. Stent Thrombosis | 5.9% (9) | 7.6% (13) | 0.55 | 2.6% (19) | 5.5% (40) | <0.01 |
| MACE (Primary Endpoint) | 24.8% (38) | 34.3% (59) | 0.06 | 17.1% (127) | 23.0% (168) | <0.01 |

**Conclusions:** At 5-years EES was superior with regards to efficacy and safety to PES in non-diabetic patients. In diabetic patients a late trend towards reduction of MACE was observed with EES compared to PES, mainly driven by a lower rate of TVR.

## TCT-590

### Three-Year Clinical Follow-Up of the FIREHAWK Abluminal Groove-Filled Biodegradable Polymer Sirolimus-Eluting Stent in the Treatment of Single De Novo Native Coronary Lesions: The TARGET I Trial

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**Background:** We sought to investigate the long-term outcomes of an abluminal groove-filled biodegradable polymer sirolimus-eluting stent FIREHAWK (MicroPort Medical, Shanghai, China) compared to an everolimus-eluting stent (EES) XIENCE V in the randomized TARGET I trial.
**Methods:** A total of 458 patients with single de novo native coronary lesions < =24 mm in length and a coronary artery >=2.25 to < =4.0 mm in diameter were enrolled in the TARGET I study, a prospective, randomized, non-inferiority trial. The primary endpoint was in-stent late lumen loss (LLL) at 9-month follow-up. The secondary endpoint, target lesion failure (TLF), was defined as the composite of cardiac death, target vessel myocardial infarction (TV-MI), and ischemia-driven target lesion revascularization (iTLR). Clinical follow-up was scheduled at 1-, 6- and 12-month, and annually up to 5 years for all enrolled patients. All adverse clinical events were adjudicated by an independent committee.
**Results:** Previously reported results demonstrated FIREHAWK stent was non-inferior to XIENCE V EES for the primary endpoint of 9-month in-stent LLL (0.13±0.24 mm vs. 0.13±0.18 mm, p=0.94; difference and 95% confidence interval 0.00 [-0.04, 0.04] mm; p for non-inferiority < 0.0001), and had a comparable clinical outcome at 2 years. There were still no significant differences between the two groups up to 3 years, and no definite/probable stent thrombosis occurred in FIREHAWK group. (Table)

**Table. Clinical Outcomes through 3 Years**

| | 1 Year | | | 2 Years | | | 3 Years | | |
|---|---|---|---|---|---|---|---|---|---|
| | FIREHAWK, n=227 | XIENCE V, n=231 | p | FIREHAWK, n=226 | XIENCE V, n=231 | p | FIREHAWK, n=221 | XIENCE V, n=228 | p |
| Clinical Follow-Up, % (n/N) | 99.6 (226/227) | 100 (231/231) | 0.50 | 99.6 (226/227) | 100 (231/231) | 0.50 | 97.4 (221/227) | 98.7 (228/231) | 0.34 |
| Death, % (n) | 0.4 (1) | 0.9 (2) | 1.00 | 0.4 (1) | 0.9 (2) | 1.00 | 1.8 (4) | 1.8 (4) | 1.00 |
| Cardiac Death | 0.4 (1) | 0 (0) | 1.00 | 0.4 (1) | 0 (0) | 1.00 | 0.9 (2) | 0.4 (1) | 0.62 |
| Myocardial Infarction, % (n) | 1.3 (3) | 2.2 (5) | 0.72 | 1.3 (3) | 2.6 (6) | 0.50 | 1.4 (3) | 3.1 (7) | 0.34 |
| Q Wave MI | 0 (0) | 0 (0) | - | 0 (0) | 0 (0) | - | 0.0 (0) | 0.4 (1) | 1.00 |
| Non Q Wave MI | 1.3 (3) | 2.2 (5) | 0.72 | 1.3 (3) | 2.6 (6) | 0.50 | 1.4 (3) | 2.6 (6) | 0.50 |
| TV-MI | 1.3 (3) | 1.7 (4) | 1.00 | 1.3 (3) | 1.7 (4) | 1.00 | 1.4 (3) | 2.2 (5) | 0.72 |
| ITLR, % (n) | 0.4 (1) | 0.4 (1) | 1.00 | 0.9 (2) | 0.9 (2) | 1.00 | 1.8 (4) | 1.3 (3) | 0.75 |
| Any Revascularization, % (n) | 1.8 (4) | 4.8 (11) | 0.07 | 2.2 (5) | 6.1 (14) | 0.04 | 4.5 (10) | 7.5 (17) | 0.19 |
| TLF, % (n) | 2.2 (5) | 2.2 (5) | 1.00 | 2.7 (6) | 2.6 (6) | 0.97 | 4.1 (9) | 3.5 (8) | 0.75 |
| PoCE (composite of all cause death, all MI, and any revascularization), % (n) | 3.5 (8) | 7.4 (17) | 0.07 | 4.0 (9) | 8.7 (20) | 0.04 | 7.2 (16) | 11.0 (25) | 0.17 |
| Definite/Probable Stent Thrombosis, % (n) | 0 (0) | 0 (0) | - | 0 (0) | 0 (0) | - | 0.0 (0) | 0.4 (1) | 1.00 |

**Conclusions:** In the multicenter randomized TARGET I trial, the 3-year follow-up results confirmed that the novel FIREHAWK stent had a durable safety and efficacy profile, which was comparable to the XIENCE V EES for the treatment of single de novo native coronary lesions. (ClinicalTrials.gov Identifier: NCT01196819)

## TCT-591

### Safety and Efficacy of the biodegradable polymer Biolimus-eluting stent versus the durable polymer Everolimus-eluting stent in all-comers undergoing PCI: Pooled analysis of the COMPARE II and NEXT trials at 1 year

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**Background:** Drug-eluting stents with biodegradable polymers have been developed to reduce the risk of very late adverse events. Distinct studies have indicated non-inferiority of the biodegradable polymer-coated biolimus-eluting stent (Nobori™; BES) compared to the durable polymer-coated everolimus-eluting stent (Xience™ or Promus™; EES) with regards to safety and efficacy at 1 year. However, these trials were not powered to detect differences in low-frequency events.
**Methods:** The all-comers COMPARE II and NEXT clinical trials randomly assigned 5942 patients to BES or EES and is at present the largest pooled analysis of BES in all-comers requiring percutaneous coronary intervention (PCI). The pre-specified composite endpoint was target vessel failure (TVF) defined as cardiac death, target vessel related myocardial infarction (MI), or clinical-indicated target vessel revascularization (TVR-CD).
**Results:** The pooled unadjusted 1-year clinical outcomes of the 5942 study patients (8094 lesions) are tabulated. Covariate adjusted analyses accounting for baseline imbalances between trials confirmed non-significant differences between stent type and clinical outcomes. The trend for a higher definite stent thrombosis rate in the BES group was by multivariate analysis less prominent (HR 2.05 [CI95% 0.75-5.60]; p=0.16).

| Events at 1 Year | BES (n=3412) | EES (n=2530) | P-value |
|---|---|---|---|
| All-cause death | 2.0% (68) | 2.0% (50) | 1.0 |
| Cardiac death | 1.1% (39) | 1.0% (26) | 0.71 |
| Myocardial infarction | 3.1% (104) | 2.9% (73) | 0.76 |
| Target lesion revascularization (All) | 3.4% (115) | 3.5% (88) | 0.83 |
| Target lesion revascularization (CD) | 2.5% (84) | 2.5% (63) | 1.0 |
| Target vessel revascularization (All) | 5.0% (172) | 5.0% (127) | 1.0 |
| Target vessel revascularization (CD) | 3.6% (122) | 3.8% (97) | 0.63 |
| Stent thrombosis (definite) | 0.5% (17) | 0.2% (5) | 0.08 |
| Stent thrombosis (definite / probable) | 0.5% (18) | 0.4% (10) | 0.57 |
| Target vessel failure | 6.4% (219) | 6.7% (169) | 0.71 |

**Conclusions:** At 1-year the biodegradable polymer-coated BES has similar safety and efficacy outcomes as the durable polymer-coated EES. Longer follow-up data is needed to determine the role of biodegradable polymer-coated BES in real world clinical practice.

## TCT-592

### Lower Five Year Event Rates In The Genous Endothelial Progenitor Cell Capturing Stent Compared With A Drug Eluting Stent In De-novo Coronary Artery Lesions With A High-risk Of Restenosis; A Randomized Controlled Trial

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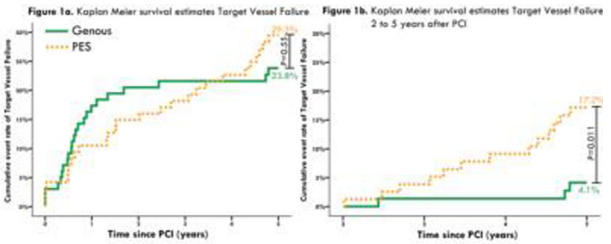
**Background:** These are the first long-term randomized adjudicated trial data of five year results of the Genous bio-engineered endothelial progenitor cell capturing stent (OrbusNeich BV, Fort Lauderdale, FL, USA) compared with a paclitaxel-eluting stent(PES).
**Methods:** In this prospective randomized trial, patients with de-novo coronary artery lesions carrying a high risk of restenosis (chronic total occlusion,lesion length > 23mm,vessel diameter < 2.8mm or any lesion in a diabetic patient) were randomized 1:1 to the Genous or a PES. The current primary endpoint is adjudicated target vessel failure (TVF) at 5-years, a composite of cardiac death, myocardial infarction (MI) and target vessel revascularization. Clinical event rates were estimated by Kaplan-Meier method and compared with a log-rank test.
**Results:** A total of 193 patients were included with complete follow-up in 97% of the subjects. The primary endpoint of TVF was similar at 5 years with Genous 23.8% vs

PES 29.5% (p=0.55, fig 1a). The event rate between 2 and 5 years was lower in Genous 4.1% vs PES 17.2%(p=0.011, fig 1b). The composite of death and MI was 6.3% in Genous vs 12.0% in PES (p=0.19). Definite stent thrombosis was observed in 4 cases in PES versus non in Genous.




**Conclusions:** The first randomized and adjudicated long-term results of the Genous versus a PES at 5 years show comparable performance and safety. Between two and five years a significant higher event rate was observed in the PES group compared with the Genous group. Importantly, no definite stent thrombosis was observed in the Genous treated group, compared with four cases in the PES group.

## TCT-593

### Multi-Center, Prospective, Randomized, Single-Blind, Consecutive Enrollment Evaluation of the Elixir DESyne® Novolimus-Eluting Coronary Stent System with Durable Polymer Compared to the Endeavor Zotarolimus-Eluting Coronary Stent System: Final Results from the EXCELLA II Study

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**Background:** Evaluate the long-term safety and effectiveness of the Elixir DESyne® Novolimus-Eluting Coronary Stent System (CSS) compared to the Endeavor Zotarolimus-Eluting CSS (Medtronic, Santa Rosa, CA) through assessment of clinical, angiographic, and IVUS endpoints through 5 years.
**Methods:** 210 patients were randomized 2:1 either to the DESyne CSS loaded with 5 mcg/mm of stent length of Novolimus, a sirolimus metabolite, eluted via a durable methacrylate polymer, or to the Endeavor CSS loaded with 10 mcg/mm of stent length of Zotarolimus eluted via a durable phosphoryl choline polymer. All patients were analyzed for the primary endpoint of late lumen loss (LLL) assessed by QCA at 9 months. All patients also underwent evaluation for secondary endpoints, which included a device-orientated composite endpoint (DoCE) defined as: cardiac death; target vessel MI; clinically-indicated target lesion revascularization (TLR); clinically-indicated target vessel revascularization (TVR); and stent thrombosis all evaluated at 1, 6, 9, and 12 months and annually through 5 years. In-stent and in-segment LLL were assessed at 9 months. A subset of patients underwent IVUS evaluation 9 months.
**Results:** The study met the non-inferiority endpoint and also demonstrated superiority of the DESyne CSS as compared to control. Table 1 summarizes angiographic, IVUS, and clinical results through 4 years.

**Table 1. Angiographic, IVUS and Clinical Results**

| | DESyne | Endeavor | p-value |
|---|---|---|---|
| **Angiographic Results** | | | |
| Baseline RVD (post-procedure) | 2.84±0.43 | 2.91±0.38 | 0.2 |
| **9-month angiographic/IVUS** | | | |
| In-stent Late Lumen Loss | 0.11±0.32 | 0.63±0.42 | < 0.001 |
| % neointimal volume | 4.5±5.1 | 20.9±11.3 | <0.001 |
| **Clinical Results** | | | |
| 12-month DoCE (%) | 4.3 | 7 | 0.51 |
| Clinically-indicated TLR | 1.4 | 5.6 | 0.18 |
| 24-month DoCE (%) | 4.3 | 9 | 0.14 |
| Clinically-indicated TLR | 1.4 | 7 | 0.04 |
| 36-month DoCE (%) | 5 | 12.7 | 0.057 |
| Clinically-indicated TLR | 1.4 | 9.9 | 0.008 |
| 48-month DoCE (%) | 6.5 | 12.7 | 0.19 |
| Clinically-indicated TLR | 2.2 | 8.5 | 0.06 |

**Conclusions:** The DESyne CSS met the non-inferiority endpoint and also demonstrated superiority as compared to Endeavor at 9 months. Clinical results through 4 years demonstrated lower DoCE (6.5 and 12.7, p=0.19) and significantly lower clinically-indicated TLR (2.2 and 8.5 p=0.06) for DESyne vs Endeavor. Final clinical results through 5 years will be presented.

## TCT-594

### Five year and Final Report of BioFreedom First-In-Man, a Randomized Trial comparing Polymer-Free BioFreedom™ stents with Durable Polymer Taxus Liberté™ Stents

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**Background:** US guidelines recommend 12 months of uninterrupted DAPT after implantation of DES. Prolonged and more powerful DAPT regimens have offered benefit by reducing VLST, but at the cost of increased risk of bleeding. There is an emerging need for new stents that are less dependent on prolonged DAPT. The BioFreedom™ stent (BFD) releases Biolimus A9™, without using a polymer or binder. Based on an animal model, 98% of the drug diffuses to the vessel wall within 1 month, leaving a BMS in place. This is generating the hypothesis that BFD can be associated with a need for shorter DAPT and safety advantage compared to a polymer based DES. This First-In-Man trial aims to demonstrate the safety and effectiveness of the BFD compared to the Taxus Liberté™ pactilaxel-eluting stent (PES).
**Methods:** BioFreedom FIM is a prospective, multi-center, randomized trial. 182 patients were enrolled and randomized to BFD Standard Dose (SD, 15.6 µg/mm), or BFD Low Dose (LD, 7.8 µg/mm), or Taxus Liberté™ DES. The primary endpoint was in-stent Late Loss (LL) at 12 months. The main secondary endpoints are IVUS neointimal volume at 4 & 12 months; MACE (death, MI, emergent bypass or clinically-driven TLR) and ST rates (ARC defined) at 30 days, 4 and 12 months, and then yearly up to 5 years.
**Results:** The in-stent LL was non inferior in BFD SD (p non-inf = 0.001) and trended towards superiority with medians of 0.17mm [0.09, 0.39] vs. 0.35mm [0.22, 0.57] compared to PES (p sup=0.11) at 12 months. At 4 years, the clinical FU was 93.5%. The BFD SD and PES showed similar rates of MACE (BFD SD 13.6% vs. PES 13.3%, p=1.02) with no definite/probable ST in any groups. Interestingly, at 2 years, there was a significant difference in adherence to DAPT between the groups (BFD SD 5.2% vs. PES 18.6%, p=0.025) which disappeared at further follow-ups.
**Conclusions:** The safety and efficacy of the polymer free BioFreedom has been shown out to 4 years. A large randomized clinical trial (LEADERS FREE) is currently studying the possibility of using this stent in patients with high bleeding risk, unable to tolerate a prolonged course of DAPT. The 5-year final results of BioFreedom FIM will be reported for the 1st time during this presentation.